PATENTLY OURS? CONSTITUTIONAL CHALLENGES TO DNA PATENTS

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> There has never been a challenge to the principle of equal opportunity as powerful as the threat posed by [genetic] technologies, with the possible, hardly democratic, exception of slavery.
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> —Maxwell J. Mehlman and Jeffrey R. Botkin[1]

INTRODUCTION

The controversy surrounding patenting deoxyribonucleic acid ("DNA") is hardly new. The first patent on a gene was granted by the United States Patent and Trademark Office ("PTO") two decades ago, in 1982.[2] As biological research was advancing rapidly in the 1980s, two trends combined to encourage the patenting and commercialization of DNA: the passage of pro-economic growth legislation and the emergence of the biotechnology industry.[3] Since then, the PTO has granted over 40,000 patents on DNA,[4] a practice that some say "challenge[s] [the] longstanding norms of sharing and openness" in biological research.[5] Add to that concerns that DNA patents may stifle development in the name of commercial gain,[6] offend the inherently personal nature of DNA, and raise bioethical dilem-

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1 MAXWELL J. MEHLMAN & JEFFREY R. BOTKIN, ACCESS TO THE GENOME: THE CHALLENGE TO EQUALITY 105 (1998).

2 *See* U.S. Patent No. 4,322,499 (filed Dec. 22, 1978) (issued Mar. 30, 1982) (claiming a recombinant plasmid comprising the endorphin gene sequence).

3 NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 43–49 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006) [hereinafter REAPING THE BENEFITS] (naming the Stevenson-Wydler Technology Innovation Act and the Patent and Trademark Amendments of 1980 as examples of pro-economic growth laws that helped incentivize the patenting of biological technology).

4 Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 19 (2011).

5 REAPING THE BENEFITS, *supra* note 3, at 44.

6 *Id.* at 25.

mas, and it becomes apparent why patents on DNA and genetic testing methods (collectively, "DNA patents")[7] have remained so controversial.[8] Many advocates have even declared DNA to be common to the global human heritage.[9]

The debate in the United States culminated recently in a high profile case, *Association for Molecular Pathology v. United States Patent & Trademark Office* (*Myriad*),[10] in which the plaintiffs contested the patentability of two breast cancer genes and related genetic testing methods.[11] According to the National Cancer Institute, a woman born today in the United States has, on average, a 12.29% risk of developing breast cancer at some point in her lifetime.[12] Genetic research by

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7 In this Comment, I use the terminology "DNA patent" rather than "gene patent" because it more accurately reflects the various types of patents on DNA-related technology. DNA patents may cover isolated genes, isolated DNA sequences, and genetic testing methods. Thus, the colloquial term "gene patent" is a misnomer when applied to the broad range of DNA-related patents. *See* David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152, 163 n.1 (2001) (highlighting the important terminology difference). Where I use the term "DNA patent" I am using the term broadly to refer to all the various types of DNA-related patents. Where I am referring a subset of those patents, I will use other terms with facially obvious meanings, such as "patents on DNA molecules" or "patents on DNA testing methods."

8 *See, e.g.*, Joseph Stiglitz & John Sulston, Op-Ed., *The Case Against Gene Patents*, WALL ST. J., Apr. 16, 2010, at A10 (arguing that DNA sequences, as naturally occurring molecules, should not be patentable); *Who Owns Your Body?*, WHOOWNSYOURBODY.ORG, http://www.whoownsyourbody.org (last visited Nov. 23, 2011) (advocating against patenting genes because of concerns about DNA ownership). *See generally* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006) (analyzing the motivations behind the "host of ethical, legal and economic concerns" surrounding DNA patenting).

9 *See, e.g.*, Universal Declaration on the Human Genome and Human Rights, G.A. Res. 53/152, U.N. Doc. A/RES/53/152 (Mar. 10, 1999) (viewing genes as belonging to the common heritage of mankind); Eur. Parl. Assoc., *Protection of the Human Genome by the Council of Europe*, 13th Sess., Recommendation 1512 (2001), *available at* http://assembly.coe.int/Documents/AdoptedText/ta01/EREC1512.htm (same); Press Release, World Medical Ass'n, *World Medical Association Council Meeting* (2000), *available at* http://www.wma.net/en/40news/20archives/2000/2000_16/index.html (same).

10 When referring to the *Ass'n for Molecular Pathology v. United States Patent & Trademark Office* case in general, I will simply use its common short name, *Myriad*. I will be more specific when referencing the separate decisions of the district court (*Myriad I*) and the Federal Circuit (*Myriad II*).

11 Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

12 N. HOWLADER ET AL., NAT'L CANCER INST., SEER CANCER STATISTICS REVIEW, 1975–2008, at tbl.4.18, *available at* http://seer.cancer.gov/csr/1975_2008/results_merged/sect_04_breast.pdf; *see also* Ass'n for Molecular Pathology v. USPTO (*Myriad II*), 653 F. 3d at 1339 ("The average woman in the United States has around a twelve to thirteen percent risk of developing breast cancer in her lifetime."), *petition for cert. filed* (U.S. Dec. 7, 2011).

the defendants in *Myriad*, though, revealed a remarkable biological predictor: women with mutations in two specific genes—BRCA1 and BRCA2 (collectively "BRCA")—are at a significantly higher (50–80%) risk of developing breast cancer.[13] This may seem like a boon for medical research, a breakthrough in humanity's endeavor to conquer cancer. The problem for some patients, though, was that they could not obtain BRCA genetic testing—through their insurance or at an affordable price—due to patent protection on the genes and screening methods.[14] Doctors, researchers, and medical organizations also complained that their desire to provide BRCA genetic testing was hindered by fear of exposing themselves to potential patent litigation.[15]

The *Myriad* case was closely watched, as it had the far-reaching potential to block the patenting of DNA products and technologies. In 2010, to the surprise of many,[16] the district court sided with the plaintiffs on grounds that DNA, even when isolated and purified, is a product of nature and thus not patentable subject matter.[17] It was the first time any federal court found DNA patents to be invalid for ineligible subject matter. But in a blow to critics of DNA patenting, the Circuit Court for the Federal Circuit reversed much of the district court's decision the following year, holding that isolated and purified DNA molecules and certain DNA-related methods are indeed patentable subject matter.[18]

The *Myriad* cases are also notable, though, because the plaintiffs asserted some interesting constitutional arguments against DNA patents—that they violate both the First Amendment and the Patent Clause of the Constitution.[19] Under the doctrine of constitutional avoidance,[20] the district court declined to address these arguments

13 *Myriad II*, 653 F.3d at 1339; *see also Breast Cancer*, AM. CANCER SOC'Y, http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-risk-factors (last updated Sept. 29, 2011) (describing BRCA gene mutations, as well as other factors, as significant risk determinants of breast cancer).

14 *Myriad II*, 653 F.3d at 1340.

15 *Id.* at 1341.

16 *See, e.g.*, Sharon Begley, *In Surprise Ruling, Court Declares Two Gene Patents Invalid*, NEWSWEEK, Mar. 29, 2010, http://blog.newsweek.com/blogs/thehumancondition/archive/2010/03/29/in-surprise-ruling-court-declares-two-gene-patents-invalid.aspx.

17 *Myriad I*, 702 F. Supp. 2d at 220–37.

18 *Myriad II*, 653 F.3d at 1351.

19 *See Myriad I*, 702 F. Supp. 2d at 237–38 (reviewing the claim that granting the *Myriad* patents violates the Constitution's First Amendment, as well as Article I, Section 8, Clause 8).

20 *See, e.g.*, Spector Motor Serv., Inc. v. McLaughlin, 323 U.S. 101, 105 (1944) ("If there is one doctrine more deeply rooted than any other in the process of constitutional adjudi-

and reached only the issues rooted in patent doctrine.[21] In this Comment, I pick up where the court left off by extending the legal analysis to possible constitutional challenges against DNA patents. The constitutional issues that DNA patents could potentially raise are worth exploring because of the far-reaching social equality and property rights issues that genetic technologies pose. Given that isolated and purified DNA has now been deemed patentable subject matter, the battleground for DNA patenting in the future may lie in constitutional arguments. And, at the least, a consideration of constitutionality will deepen the existing debate on DNA patents.

Part I provides some technical background and historical perspective on genetics and DNA patenting. Part II examines possible constitutional challenges to DNA patents and makes a determination as to whether any of them might prevail. I focus in particular on the most controversial type of DNA patents—those that claim isolated and purified human DNA sequences.[22] Part III then raises some issues that developing genetic technologies and DNA patents may present in the future.

I conclude that constitutional challenges to DNA patents are unlikely to succeed at this time, but, as social perceptions and access to the fruits of genetic research continue to evolve, constitutional arguments could gain more traction in the future.

I. BACKGROUND

A. The Structure of DNA

In order to appreciate the nuances of DNA patents, a brief understanding of genetics is helpful. DNA stores genetic information, the basis of inheritance,[23] in nearly all organisms.[24] In nature, it exists as a

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cation, it is that we ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable.").

21 *See Myriad I*, 702 F. Supp. 2d at 237–38 (dismissing plaintiffs' constitutional arguments under the doctrine of constitutional avoidance).

22 *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005) ("[The] gene patents that seem to cause the most controversy are those claiming human protein-encoding nucleotide sequences."); *see also* text accompanying notes 97–106.

23 Genes are defined as the "functional unit of inheritance." MERRIAM-WEBSTER'S MEDICAL DICTIONARY, http://www2.merriam-webster.com/cgi-bin/mwmedsamp (search: "gene") (last visited Nov. 23, 2011).

24 There are exceptions to this rule—some viruses have RNA rather than DNA as their genetic material. WILLIAM S. KLUG, MICHAEL R. CUMMINGS & CHARLOTTE A. SPENCER, CONCEPTS OF GENETICS 240–41 (8th ed. 2006).

double helix molecule comprised of nucleic acids that encode instructions for living cells to make proteins,[25] which are necessary for structure and biological processes.[26]

The building blocks of DNA are nucleotides, which consist of a sugar (deoxyribose), a phosphate, and a nitrogenous base.[27] There are four nitrogenous bases—adenine ("A"), thymine ("T"), cytosine ("C"), and guanine ("G")—often referred to as the genetic alphabet or genetic code.[28] Nucleotides are named after the base that they contain and are linked by covalent sugar-phosphate bonds to form a polynucleotide chain, or DNA strand.[29] As a double helix, a DNA molecule resembles a twisted ladder and contains two complementary DNA strands.[30] The complementary pairing refers to the bases always pairing together, or hybridizing, in a complementary relationship—A with T, and C with G—to form the "rungs" of the ladder-like molecule.[31]

In vivo, DNA molecules are tightly packed into cell nuclei as chromosomes.[32] Humans have twenty-three pairs of chromosomes: twenty-two pairs of autosomal chromosomes and one pair of sex chromosomes (either two X chromosomes in females, or one X and one Y chromosome in males). Together, these chromosomes form the human genome, which contains an estimated 20,000–25,000 protein-encoding genes.[33] Nearly all cells in the human body contain the entire genome, but different types of cells express different genes.[34]

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25 DNA is first converted into ribonucleic acid, or RNA, and then translated into a protein product. *Id.* at 6.

26 *Id.*

27 *Id.* at 5. Without a phosphate, the subunit is called a nucleoside rather than a nucleotide. *Id.* at 241.

28 *Id.* at 5.

29 *Id.* at 241–44.

30 *Id.* at 5.

31 *Id.* at 5, 241.

32 *Id.* at 20–22. If unwound and stretched out linearly, the DNA in each somatic (diploid) human cell would be approximately two meters long, and all the DNA in one individual would stretch to and from the sun more than three hundred times. Anthony T. Annunziato, *DNA Packaging: Nucleosomes and Chromatin*, 1 NATURE EDUC. (2008), *available at* http://www.nature.com/scitable/topicpage/dna-packaging-nucleosomes-and-chromatin-310.

33 *How Many Genes Are in the Human Genome?*, U.S. DEP'T OF ENERGY, http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml (last modified Sept. 19, 2008).

34 KLUG, CUMMINGS & SPENCER, *supra* note 24, at 412–13.

B. The Role of Genes

A gene is difficult to define because it gives rise to both scientific and abstract notions.[35] Biologically, it is a segment of DNA, anywhere from a few nucleotides to several thousand nucleotides long, that codes for a specific protein. If nucleotides are roughly analogous to letters of the alphabet, then genes would be words, chromosomes would be paragraphs, and genomes would be entire passages. A gene contains regions that can be identified as introns, or intervening sequences that do not code for any protein; all other regions are exons, or essential portions that code for a protein.[36] Proteins, in turn, "are responsible for imparting the properties that we attribute to living systems."[37] There are a wide range of proteins, including enzymes, hormones, structural molecules, connective tissues, and antibodies.[38] The process of going from DNA to its end product, protein, is called gene expression and involves two main steps: (1) transcription and (2) translation.[39]

During transcription, the DNA molecule is unwound and transcribed into a different type of nucleic acid, ribonucleic acid ("RNA"). RNA is similar to DNA, except that its nucleotide backbone consists of the ribose, rather than deoxyribose, sugar, and it contains the base uracil ("U") rather than T.[40] The non-coding strand of DNA is used as a template to form a pre-RNA molecule, which has exactly the complementary base sequence.[41] The pre-RNA molecule is then spliced to remove all the unnecessary regions, or introns.[42] The resulting RNA molecule, containing only exons, is called messenger RNA ("mRNA").[43]

After transcription, an mRNA molecule is converted into a protein in a process called translation. Each triplet of nucleotides on an mRNA molecule is called a codon and codes for one of twenty amino acids, the building blocks of proteins.[44] A transfer RNA ("tRNA") attaches to the mRNA, interprets a codon, directs the corresponding amino acid to be added to a growing polypeptide, then continues

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35 Rogers, *supra* note 4, at 21–22 (discussing the challenge of defining "genes").

36 KLUG, CUMMINGS & SPENCER, *supra* note 24, at 323.

37 *Id.* at 6.

38 *Id.*

39 *Id.* at 5–6.

40 *Id.* at 241.

41 *Id.* at 320. For example, a non-coding DNA sequence of AGTCAAT would be transcribed into an RNA molecule with a sequence of UCAGUUA.

42 *Id.* at 323.

43 *Id.* at 308, 320, 323.

44 *Id.* at 307–08.

down the mRNA until the entire sequence has been translated into a complete protein.[45]

Finally, a mutation refers to a change of base in a DNA sequence, which may or may not result in the sequence encoding a different polypeptide product.[46] Gene mutations are frequently responsible for biological abnormalities and genetic diseases.

C. Advances in Biotechnology

For several decades now, scientists have been able to identify, study, and manipulate DNA molecules for medical applications. "DNA sequencing" or "gene sequencing" refers to the process of determining the precise order of bases in a DNA segment or gene.[47] Scientists are also able to synthesize DNA sequences in vitro. One common method of doing so is to use mRNA as a template to create complementary DNA ("cDNA") in a type of reverse-transcription process. Such cDNA has the advantage of not having any introns, as it is created from intron-free mRNA.[48]

Short DNA molecules, usually eighteen to twenty-two base pairs long,[49] can be useful as probes or primers in genetic research. They can identify target DNA sequences by annealing, or complementarily binding, to DNA molecules. Scientists have also developed various methods for DNA sequencing and genetic diagnostic testing, advancing our ability to treat genetic diseases. More than one thousand genetic diseases can now be diagnosed with genetic tests, and most of the associated genes have been patented.[50] In fact, nearly 20% of all human genes have been explicitly claimed in patents,[51] including those associated with obesity, diabetes, Alzheimer's disease, and various cancers.[52]

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45 *Id.* at 335–36.

46 The reason a mutation may not materially change the polypeptide product that a DNA sequence encodes is because several different codons may code for the same amino acid. In other words, there is redundancy, or degeneracy, in the genetic code. *See id.* at 312–14.

47 *Id.* at 110, 477.

48 *Id.* at 469.

49 *PCR Primer Design Guidelines*, PREMIER BIOSOFT, http://www.premierbiosoft.com/tech_notes/PCR_Primer_Design.html (last visited Nov. 23, 2011).

50 REAPING THE BENEFITS, *supra* note 3, at 68.

51 Jensen & Murray, *supra* note 22.

52 *Id.* at 240; Selene Kaye, *Who Owns Your Genes?*, AM. C.L. UNION BLOG RTS. (May 12, 2009, 7:45 PM), http://www.aclu.org/2009/05/12/who-owns-your-genes.

D. DNA Patenting

1. The Patentability of DNA Under Patent Law

Under § 101 of the Patent Act, "any new and useful process, machine, manufacture, or composition of matter" is patentable.[53] This language has been construed broadly by the Supreme Court[54] to encompass "anything under the sun that is made by man."[55] However, there are limitations to patentable subject matter in the form of three judicially created exceptions to § 101: "laws of nature, physical phenomena, and abstract ideas."[56] "The concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.'"[57]

Although natural phenomena are not patentable subject matter, patent eligibility may arise when a natural compound has been isolated and purified through human intervention to become a substance different in kind from the natural product.[58] In 1980, the Supreme Court held in *Diamond v. Chakrabarty* that hybrid microorganisms made through genetic engineering are patentable because, despite their living status, they are man-made and the "product of human ingenuity."[59] Under this legal framework, the

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53 35 U.S.C. § 101 (2006).

54 The Court recently reaffirmed that "[i]n choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).

55 *Chakrabarty*, 447 U.S. at 309 & n.6 (citations omitted).

56 *Id.* at 309; *see also* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (describing the exceptions as precluding patenting of "phenomena of nature," "mental processes," and "abstract intellectual concepts"). The Supreme Court, over the years, has given numerous examples of subject matter that is not patentable. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 594–95 (1978) (finding mathematical algorithm applied to catalytic convertors to be a law of nature and not patent eligible); *Gottschalk*, 409 U.S. at 71–73 (holding that numerical conversion algorithm is an abstract idea and not patentable); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (ruling that a mixture of naturally-occurring bacteria is a natural phenomena and not patentable). *But see* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (holding that a natural substance is patent eligible if it is purified and given commercial or therapeutic qualities), *aff'd in relevant part* 196 F. 496 (2d Cir. 1912).

57 *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130).

58 *See Parke-Davis & Co.*, 189 F. at 103 (finding purified adrenaline to be patent eligible because it was "for every practical purpose a new thing commercially and therapeutically"); Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 F. 701, 704 (7th Cir. 1910) (holding purified aspirin to be patent eligible because, unlike less purified aspirin, it was "practically effective and safe").

59 *Chakrabarty*, 447 U.S. at 309 (holding that man-made products of genetic engineering are patent eligible subject matter under 35 U.S.C. § 101).

PTO has been issuing patents on isolated and purified gene sequences since 1982.[60]

In 2001, the PTO published a revised set of examination procedures related to the "utility," or usefulness, requirement[61] for patentability and reiterated its position that DNA is patentable.[62] It stated that DNA that has been "isolated" and "purified" from its natural state is patentable "because that DNA molecule does not occur in that isolated form in nature."[63]

2. An Overview of the DNA Patenting Controversy

The patenting of DNA products and genetic methods has been bitterly disputed.[64] While the BRCA genes and related litigation are the most controversial DNA patenting topic to date,[65] there have been several other high profile DNA patenting controversies. For instance, there was widespread opposition to an attempt by the U.S. National Institutes of Health ("NIH") in the 1990s to patent more than two-thousand expressed sequence tags ("ESTs")—short segments of cDNA useful in gene discovery and gene sequencing.[66] Similarly, Miami Children's Hospital—holder of the gene patent for Canavan syndrome (a rare and fatal neurological disease)—caused an uproar when it decided to charge a $12.50 royalty per test for the disease.[67]

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60 *See, e.g.*, U.S. Patent No. 4,322,499 (filed Dec. 22, 1978) (issued Mar. 30, 1982).

61 *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (indicating that the utility requirement to patentability in 35 U.S.C. § 101 has been interpreted to entail "substantial" and "specific benefit").

62 Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092 (Jan. 5, 2001).

63 *Id.* at 1093.

64 *See* Caulfield et al., *supra* note 8, at 1091–94 (investigating the reasons behind common concerns about DNA patenting); Resnik, *supra* note 7, at 152 (analyzing the basis behind arguments that DNA patenting threatens human dignity); *see also supra* note 9 and accompanying text. Popular media, including novels, have also taken sides in the controversy. *See, e.g.*, MICHAEL CRICHTON, NEXT (2006) (using a mix of fiction and non-fiction in a novel about a world dominated by genetic research and corporate greed in order to advocate for a ban on DNA patenting).

65 *See* Caulfield et al., *supra* note 8, at 1093 fig.2 (comparing the number of references to various controversial biotechnology patents).

66 *See* Gert Matthijs & Gert-Jan B. Van Ommen, *Gene Patents: From Discovery to Invention: A Geneticist's View*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 311, 311–12 (Geertrui Van Overwalle ed., 2009) (describing the scientific community's generally negative reaction to NIH's attempt to patent ESTs). For general background on the controversy around patenting expressed sequence tags, see Daniel J. Kevles & Arie Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233, 236–37 (2001).

67 *See* Tom Reynolds, *Gene Patent Race Speeds Ahead Amid Controversy, Concern*, 92 J. NAT'L CANCER INST. 184, 186 (2000), *available at* http://jnci.oxfordjournals.org/content/

Critics are often concerned that DNA patenting may inhibit scientific and medical progress. Specifically, they argue that: (1) on balance, patented DNA sequences may stall rather than promote medical research because of DNA's fundamental role in downstream research; and (2) patent-protected genetic tests may not be readily accessible due to licensing restrictions.[68] Some are also worried that DNA patents unethically treat humans as marketable commodities and threaten human dignity.[69] Still others maintain that genetic material should not be patentable because it is common to all humanity[70] and not created by man.[71]

92/3/184.full; *see also* Caulfield et al., *supra* note 8, at 1091 (mentioning the "furor" caused by the NIH and Canavan DNA patenting controversies).

68 *See* Rogers, *supra* note 4, at 19–20 ("The advent of human gene patents frightened many people who feared: 1) inhibition of scientific research, the development of medical therapies and follow-on technologies; 2) unreasonable costs for genetic tests, lower quality genetic tests, or worse the exclusion of genetic tests from patients; and 3) stealing of publicly funded research by corporations."); *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–701 (1998) (discussing a scenario where researchers underuse scarce biomedical resources because too many owners can block each other); Lori Andrews & Jordan Paradise, *Genetic Sequence Patents: Historical Justification and Current Impacts*, 35–36 (2009), *available at* http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID1632539_code512260.pdf?abstractid=1632539 (making legal arguments against DNA patents); Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 241–46 (2003) (noting that gene patents are contrary to the underlying intent of the Patent Act and that traditional economic analysis does not support the application of the patent system to genes). For a discussion of patent protection's impact on research and access, see *supra* Part II.A.

69 *See generally* Resnik, *supra* note 7, at 163 (describing the threat that DNA patenting may pose to human dignity).

70 *See, e.g.*, *Position Statement on Gene Patents and Accessibility of Gene Testing*, AM. COLL. OF MED. GENETICS (Aug. 2, 1999), http://www.acmg.net/StaticContent/StaticPages/Gene_Patents.pdf; Bartha Maria Knoppers, Commentary, *Status, Sale, and Patenting of Human Genetic Material: An International Survey*, 22 NATURE GENETICS 23, 23 (1999) (relaying that the human genome "can be defined at the universal level, the family level, and the individual level" and "definitive legal recognition of the human genome as common heritage has not been formalized. . . . In contrast to the hesitancy to adopt the notion of the universal, 'collective' human genome, the 'familial' nature of genetic material and information is slowly gaining acceptance," especially at the international level.).

71 For example, in 1995, the leaders of more than eighty various religious faiths and denominations signed a joint statement, declaring: "We, the undersigned religious leaders, oppose the patenting of human and animal life forms. . . . We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions." Press Release, Gen. Bd. of Church & Soc'y of the United Methodist Church, Joint Appeal Against Human and Animal Patenting (May 1995), *in* AUDREY R. CHAPMAN, UNPRECEDENTED CHOICES: RELIGIOUS ETHICS AT THE FRONTIERS OF GENETIC SCIENCE 125 (1999).

Courts in the United States, though, do not conduct moral or ethical inquiries, leaving that task instead to the legislature's lawmaking.[72] As such, this Comment will address the issues surrounding DNA patents through a legal analysis, setting aside ethical issues.[73]

3. The Myriad *Decisions*

The debate over DNA patenting culminated recently in the closely watched[74] *Myriad I* and *Myriad II* cases. The high profile litigation brought the topic of DNA patenting into the spotlight, prompting several organizations, both domestically[75] and abroad,[76] to publish reports with policy recommendations.[77]

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72 Resnik, *supra* note 7, at 153.

73 For a discussion of ethical issues, see, for example, Resnik, *supra* note 7. Resnik's scholarship finds that human DNA patenting does not "*violate*" human dignity but may "*threaten*" it because DNA patenting may "play[] a role in the trend toward commodification of the body." *Id.* at 163.

74 One review of DNA patenting controversies rated the *Myriad* case "the most referenced patent controversy in . . . policy documents." Caulfield et al., *supra* note 8, at 1091.

75 For example, the National Academy of Sciences has recommended a research exemption for DNA patenting to address the purported anticommons and restricted access problems. *See* REAPING THE BENEFITS, *supra* note 3, at 145.

76 For example, in the United Kingdom, the Nuffield Council on Bioethics recommended that the scope of patent rights over naturally occurring DNA and DNA as research tools should be limited and discouraged, respectively. NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA: A DISCUSSION PAPER 71–74 (2002), *available at* http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper.pdf; *see also* DANISH COUNCIL OF ETHICS, PATENTING HUMAN GENES AND STEM CELLS (2004), *available at* http://etiskraad.dk/~/media/publications-en/stem-cell-research/patenting-human-genes-and-stem-cells-2004.ashx.

77 Caulfield et al., *supra* note 8, at 1093 ("[Our] survey of policy reports reveals that the Myriad Genetics controversy was used as a primary tool for justifying patent reform . . . ."). Belgium has adopted a broad research exemption and a compulsory licensing system, "largely inspired" by Myriad's restrictive licensing policy. GEERTRUI VAN OVERWALLE & ESTHER VAN ZIMMEREN, RESHAPING BELGIAN PATENT LAW: THE REVISION OF THE RESEARCH EXEMPTION AND THE INTRODUCTION OF A COMPULSORY LICENSE FOR PUBLIC HEALTH 2 (2006), *available at* http://www.iip.or.jp/e/e_publication/pdf/vol64_overwalle_and_zimmeren.pdf. France has adopted Directive 98/44, aimed at limiting the scope of patent claims on DNA molecules more so than other European countries. *See* Jacques Warcoin, *'Patent Tsunami' in the Field of Genetic Diagnostics: A Patent Practitioner's View*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES, *supra* note 67, at 331, 333–35.

a. Background on the *Myriad* Case

At issue in the *Myriad* case were fifteen claims from seven patents, all relating to the two BRCA genes: claims 1, 2, 5, 6, 7, and 20 of U.S. Patent 5,747,282; claims 1, 6, and 7 of U.S. Patent 5,837,492; claim 1 of U.S. Patent 5,693,473; claim 1 of U.S. Patent 5,709,999; claim 1 of U.S. Patent 5,710,001; claim 1 of U.S. Patent 5,753,441; and claims 1 and 2 of U.S. Patent 6,033,857.[78] All of the claims were related to two human breast cancer genes, BRCA1 and BRCA2.[79] Using positional cloning techniques, the inventors found that mutations in the BRCA genes correlate with a significantly increased risk of ovarian and breast cancer.[80]

The plaintiffs-appellees in *Myriad* included professors, genetic counselors, breast cancer patients, and private organizations dedicated to the interests of geneticists, pathologists, and breast cancer patients.[81] Represented by the American Civil Liberties Union ("ACLU"), they filed suit against the PTO, Myriad Genetics ("Myriad"), and the directors of the University of Utah Research Foundation, arguing that the DNA patents at issue covered invalid subject matter under § 101 because the BRCA genes fell within the products-of-nature exception to patentability.[82] A threshold issue arose as to whether the plaintiffs had proper standing to bring the lawsuit, but this Comment will focus on the matters of patentability that arose after the courts resolved the standing issue.[83]

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78 Ass'n for Molecular Pathology v. USPTO (*Myriad II*), 653 F.3d 1329, 1334 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

79 *Id.*

80 While the average risk of an American woman developing breast cancer in her lifetime is 12–13%, a woman with BRCA mutations is at a 50–80% risk of developing breast cancer and a 20–50% risk of developing ovarian cancer. *Id.* at 1339.

81 *Myriad I*, 702 F. Supp. 2d at 186–89 (S.D.N.Y. 2010), *rev'd in part and aff'd in part* 653 F.3d 1329 (Fed. Cir. 2011).

82 *Id.* at 183–84.

83 Briefly, the standing issue arose because the plaintiffs-appellees were seeking a declaratory judgment when it was not clear whether the action satisfied the case-or-controversy requirement of Article III. *Myriad II*, 653 F.3d at 1341. Two of the plaintiffs-appellees, Drs. Kazazian and Ganguly, were the co-directors of the University of Pennsylvania's Genetic Diagnostic Laboratory who had stopped providing BRCA diagnostic services to women after receiving cease-and-desist letters from Myriad. *Id.* at 1339–40. They alleged that, if it were not for the threat of patent infringement litigation, they would have "the personnel, expertise, and facilities as well as the desire" to provide such diagnostic services again. *Id.* at 1340–41. Another plaintiff-appellee, Dr. Ostrer, was forced to send patient samples for BRCA testing to Myriad after the University of Pennsylvania stopped performing the tests. *Id.* at 1340. He claimed that he "would immediately begin to perform BRCA1/2-related genetic testing upon invalidation of the Myriad patents." *Id.* at 1341 (citation omitted) (internal quotation marks omitted). The defendants-appellants asserted that the plain-

The Department of Justice ("DOJ") filed an amicus brief in the case on October 29, 2010 that partially reversed the government's stance on DNA patentability.[84] The amicus brief made a distinction, on the one hand, between DNA that is isolated and altered, and, on the other hand, DNA that has simply been isolated.[85] It argued that isolated *and altered* DNA should be patentable, whereas DNA that is simply isolated should not be patentable, even though "this conclusion is contrary to the longstanding practice of the [PTO], as well as the practice of the NIH and other government agencies."[86] The PTO did not sign off on the amicus brief, so its opinion of the DOJ's brief is unclear.[87] However, as Judge Bryson pointed out in his dissenting opinion in *Myriad II*, the PTO is, after all, under the auspices of the DOJ.[88] Therefore, it could be "fair to assume that the Executive Branch has modified its position from the one taken by the PTO in its 2001 guidelines and, informally, before that."[89]

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tiffs-appellees had no adverse legal interests and had not alleged any "controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 1343. The lower court disagreed, finding standing for all the plaintiff researchers under the "all the circumstances" test of *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007), because they were "ready, willing, and able" to begin BRCA gene testing. *Myriad I*, 669 F. Supp. 2d at 386, 390–91. On appeal, the Federal Circuit affirmed in part and reversed in part on the standing issue, finding that Drs. Kazazian and Ganguly did not have standing but that Dr. Ostrer did. *Myriad II*, 653 F.3d at 1348 ("Simply disagreeing with the existence of a patent or even suffering an attenuated, nonproximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.") (referencing *MedImmune*, 549 U.S. at 127).

84 Andrew Pollack, *U.S. Says Genes Should Not Be Eligible for Patenting*, N.Y. TIMES, Oct. 29, 2010, http://www.nytimes.com/2010/10/30/business/30drug.html. The DOJ is not the only government agency that has recently reconsidered its stance on DNA patenting. For example, in 2002, a Canadian government report suggested reforms to strengthen the research exemption and loosen the compulsory licensing provisions in Canada's patent laws to allow for less restrictions on genetic diagnostic and screening tests. *See* GOV'T OF ONTARIO, ONTARIO REPORT TO THE PREMIERS: GENETICS, TESTING & GENE PATENTING: CHARTING NEW TERRITORY IN HEALTHCARE 45–52 (2002) (recommending development of new policies and training on gene patents within the Canadian Intellectual Property Office and suggesting certain amendments to the Canadian Patent Act).

85 Brief for United States as Amicus Curiae in Support of Neither Party at 4, *Myriad II*, 653 F.3d 1329 (No. 09-CV-4515).

86 *Id.* at 17–18.

87 *Id.*

88 *Myriad II*, 653 F.3d at 1380–81 (Bryson, J., concurring in part and dissenting in part).

89 *Id.*

b. The Current Validity of DNA Patenting After the *Myriad* Cases

In *Myriad I*, Judge Sweet of the Southern District of New York held the patents on the BRCA genes to be invalid. The lower court's decision was surprising, as no court had ever before found DNA patents invalid.[90] The district court viewed the BRCA genes as products of nature and thus found that the patents covered ineligible subject matter under 35 U.S.C. § 101.[91]

On appeal, the Federal Circuit reviewed the patentability of DNA subject matter in detail and overturned much of the district court's ruling in a 1-1-1 split decision.[92] It found that DNA molecules "that human intervention has given markedly different, or distinctive, characteristics" are patentable and so are related methods, as long as they claim more than simply analyzing or comparing DNA molecules.[93]

The judges in *Myriad II* made distinctions between the three types of DNA patents at issue: (1) composition claims covering isolated gene sequences; (2) method claims covering "analyzing" or "comparing" normal sequences with mutated sequences; and (3) method claims covering more than merely "analyzing" or "comparing" sequences.[94] All three judges agreed in separately authored opinions that method claims for "analyzing" or "comparing" DNA sequences are not patentable subject matter because they are overly broad for claiming "only abstract mental processes."[95] On the other hand, they found that any method claims going *beyond* merely analyzing or comparing DNA sequences are protectable by the Patent Act because they cover potentially valuable inventive methods.[96]

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90 *See* Begley, *supra* note 16 (describing the prevailing expectation of the legal community that the DNA patents at issue in *Myriad* would be upheld).

91 Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181, 220–37 (S.D.N.Y. 2010), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

92 *Myriad II*, 653 F.3d at 1333, 1358, 1373.

93 *Id.* at 1351–52 (internal quotation marks omitted).

94 *Id.* at 1334–35.

95 *Id.* at 1355–57; *id.* at 1358 (Moore, J., concurring in part); *id.* at 1373 (Bryson, J., concurring in part and dissenting in part).

96 *Id.* at 1358; *id.* at 1358 (Moore, J., concurring in part); *id.* at 1373 (Bryson, J., concurring in part and dissenting in part).

However, the composition claims at issue proved much more divisive for the court.[97] Judge Lourie's opinion for the court, with which Judge Moore concurred, found that all isolated DNA molecules are patentable, regardless of sequence length, because the covalent bonds at the ends of a DNA molecule, when isolated, must be broken, making the molecule a "distinct chemical entity" that is by definition "markedly different" from any DNA molecules existing in nature.[98] Judge Lourie was careful to note, however, that "isolated DNA is not purified DNA."[99] Purification, which "makes pure what was . . . previously impure," is distinct from the chemical manipulation of the isolation process and is not the deciding factor of patentability for DNA molecules.[100]

Judge Bryson disagreed with the plurality's view on the patentability of composition claims covering isolated DNA molecules.[101] He focused on the "material[ity of] change made to genes from their natural state," rather than the chemical alterations.[102] From such a vantage point, he agreed with Judges Lourie and Moore to the extent that a cDNA molecule that cannot be found naturally in cells should be patentable subject matter.[103] A cDNA molecule must be synthesized by man from mRNA and, as such, is arguably distinct from any native DNA because it has no introns.[104] However, an isolated gene in its entirety should not be patentable, Judge Bryson argued, because, though the ends of the DNA molecule are slightly altered chemically, an isolated gene is not a "new" entity in genetic terms; instead, it codes for the same protein as the naturally occurring gene.[105]

Therefore, the judges in *Myriad II* agreed (though their reasoning was different) that cDNA molecules are patentable, as are method claims that go beyond simply "analyzing" or "comparing" DNA sequences. They diverged, though, on the patentability of isolated DNA molecules that, except for isolation, can be found as native DNA. Not only are patents on isolated DNA molecules the most controversial, but they also "confer[] the broadest protection . . . because

97 *See id.* at 1349–55 (opinion for the court) (finding the composition claims protectable); *id.* at 1364–73 (Moore, J., concurring in part) (same); *id.* at 1375–79 (Bryson, J., concurring in part and dissenting in part) (finding the composition claims non-protectable).

98 *Id.* at 1351 (opinion for the court).

99 *Id.* at 1352.

100 *Id.*

101 *Id.* at 1373 (Bryson, J., concurring in part and dissenting in part).

102 *Id.* at 1375.

103 *Id.* at 1378–79.

104 *Id.* at 1379.

105 *Id.* at 1376–77.

the claimed molecule will fall within the scope of the patent regardless of what process is used to make the product."[106]

The case gained a lot of publicity[107] because the lower court's decision had marked the first time a federal court invalidated any patent on an isolated gene. The case was also interesting, though, because the plaintiffs raised constitutional arguments, in addition to statutory ones, in support of invalidation.[108] The plaintiffs presented arguments against DNA patentability under Article I, Section 8, Clause 8 of the U.S. Constitution (the "Patent Clause") and the First Amendment of the Constitution.[109] Under the doctrine of constitutional avoidance,[110] the district court sidestepped the constitutional issues raised by the plaintiffs.[111]

While constitutional challenges have been raised previously in other patent contexts[112] and are not uncommon,[113] no court has yet analyzed the constitutionality of DNA patents. Thus, an interesting question arises: assuming DNA patents are valid under the *Chakrabarty* framework and statutory requirements, is there something fundamentally unique about them that would nonetheless make them unconstitutional? To examine this question, this Comment will set aside statutory arguments, as well as ethical concerns.

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106 Hill, *supra* note 68, at 233.

107 *See, e.g.*, John Schwartz & Andrew Pollack, *Cancer Genes Cannot Be Patented, U.S. Judge Rules*, N.Y. TIMES, Mar. 30, 2010, at B1; Susan Decker & Thom Weidlich, *Myriad Loses Ruling Over Breast Cancer-Gene Patents (Update 3)*, BUSINESSWEEK (Mar. 29, 2010), *available at* http://www.bloomberg.com/apps/news?sid=a72pJ28MwB5c&pid=newsarchive (last visited Nov. 23, 2011); David Ewing Duncan, *Is the DNA Patent Dead?*, CNNMONEY (Mar. 30, 2011, 4:11 PM), http://tech.fortune.cnn.com/2010/03/30/is-the-dna-patent-dead.

108 Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment at 32–37, Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515 (RWS)), 2009 WL 3269113.

109 *Id.*

110 *See* Rescue Army v. Municipal Court of L.A., 331 U.S. 549, 571 (1947) (listing grounds supporting the doctrine of constitutional avoidance); *see also* Ashwander v. Tennessee Valley Auth., 297 U.S. 288, 341 (1936) (Brandeis, J., concurring) ("Considerations of propriety, as well as long-established practice, demand that we refrain from passing upon the constitutionality of an act of Congress unless obliged to do so in the proper performance of our judicial function . . . ." (internal quotation marks ommitted)).

111 Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181, 237–38 (S.D.N.Y. 2010), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

112 For example, the ACLU filed an amicus brief in *Bilski v. Kappos*, arguing that granting patents on business methods would risk violating the First Amendment. Brief for Amicus Curiae American Civil Liberties Union for Affirmance in Support of Appellee, *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (No. 2007-1130), *available at* http://www.aclu.org/files/pdfs/freespeech/in_re_bilski_aclu_amicus.pdf.

113 "It is not that unusual to invoke the Constitution in patent cases." Carter v. ALK Holdings, Inc., 605 F.3d 1319, 1329 (Fed. Cir. 2010).

This Comment assumes, pursuant to the Federal Circuit's *Myriad II* decision, that genes are patentable as a matter of patent doctrine. As such, it will not treat the issue of patentable subject matter as a separate constitutional issue.[114]

II. THE CONSTITUTIONALITY OF DNA PATENTS

Constitutional protections only apply to the government, not private entities or individuals (the "state action" doctrine).[115] Therefore, any constitutional challenge to DNA patents would necessarily have to involve the government as a party.[116] Occasionally, private action may also be considered government action, but this area of the law is unsettled and outside the scope of this Comment.[117]

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114 The Patent Clause grants Congress the power "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8. One commentator has posited that the term "useful Arts" may provide constitutional grounds for the subject matter limitation in 35 U.S.C. § 101, but the Supreme Court has not explicitly stated what constitutional grounds, if any, exist. Edward C. Walterscheid, *"Within the Limits of the Constitutional Grant": Constitutional Limitations on the Patent Power*, 9 J. INTELL. PROP. L. 291, 348–49 (2002). While "there are clearly constitutional requirements that must be met in setting standards of patentability, the nature of any constitutional restrictions on patentable subject matter is less clear." *Id.* at 292.

115 *See* The Civil Rights Cases, 109 U.S. 3, 13 (1883) (holding that, under § 5 of the Fourteenth Amendment, Congress lacks power to regulate private conduct). There are some exceptions to the "state action" rule. For example, the Thirteenth Amendment applies directly to private conduct to bar slavery. ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: POLICY AND PRINCIPLES 509 (3d ed. 2006). Also, Congress can enact laws that require private conduct to meet constitutional standards. *Id.*

116 "[W]here . . . the Government creates a corporation by special law, for the furtherance of governmental objectives, and retains for itself permanent authority to appoint a majority of the directors of that corporation, the corporation is part of the Government for purposes of the First Amendment." Lebron v. Nat'l R.R. Passenger Corp., 513 U.S. 374, 397–400 (1995) (holding that Amtrak, created by federal law with a board appointed by the President and ultimately managed by the government, must comply with the Constitution).

117 There are two general exceptions to the state action doctrine. The first exception is the "public function exception," when a private entity is performing a task traditionally and exclusively done by the government. *See* Jackson v. Metropolitan Edison Co., 419 U.S. 345, 352 (1974) (explaining the "public function exception"). The second is the "entanglement exception," requiring private conduct to comply with the Constitution if the government has authorized, encouraged, or facilitated the unconstitutional conduct. *See* Shelley v. Kraemer, 334 U.S. 1, 20, 23 (1948) (holding that judicial enforcement of discriminatory covenants constituted state action in violation of the equal protection clause of the Fourteenth Amendment); *see also Lebron*, 513 U.S. at 397 ("It surely cannot be that government, state or federal, is able to evade the most solemn obligations imposed in the Constitution by simply resorting to the corporate form.").

According to data through 2008, U.S. government institutions own 47,220 U.S. patents.[118] Of these, more than 900 are DNA-based,[119] making the U.S. government the second largest domestic holder of DNA patents, behind only the University of California.[120] When the federal government funds research at universities or institutions, the funding agreement usually specifies how patent rights will be allocated.[121] Most of the time, the research entity is the owner of the patent, but the government may retain licensing rights.[122]

In this Part, I consider four possible constitutional challenges to DNA patents based on: (1) the Patent Clause; (2) fundamental rights; (3) the First Amendment; and (4) the Takings Clause of the Fifth Amendment. The independent success of any one of the arguments could be enough to deem specific DNA patents unconstitutional, though, as I discuss below, their reach is limited and likelihood of success is low.

A. The Patent Clause (Article I, Section 8, Clause 8)

While the Constitution grants broad authority to Congress to enact patent statutes,[123] this authority is not absolute.[124] Article I, Section 8, Clause 8 of the Constitution (the "Patent Clause") contains some of the requirements of patentability. As interpreted by the Supreme Court, the Patent Clause precludes "the issuance of patents whose effects are to remove existent knowledge from the public do-

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118 PATENT TECHNOLOGY MONITORING TEAM, USPTO, UTILITY PATENTS ASSIGNED TO U.S. GOVERNMENT INSTITUTIONS, CALENDAR YEARS 1969–2008, *available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/govt/asgn/table_1_gov.htm.

119 *See* REAPING THE BENEFITS, *supra* note 3, at 104 fig.4-2.

120 *Id.*

121 Herbert J. Zeh, Jr., *The Federal Funding of R&D: Who Gets the Patent Rights?*, JOM, Apr. 1990, at 69, *available at* http://www.tms.org/pubs/journals/JOM/matters/matters-9004.html.

122 *Id.* The Bayh-Dole Act, 35 U.S.C. §§ 200–211 (2006), enacted in 1980, it allows institutions and organizations receiving federal research funding to pursue patent rights, subject to certain conditions, including granting the U.S. government a "nonexclusive, nontransferable, irrevocable, paid-up license" to the invention. 37 C.F.R. § 401.14(b) (2009).

123 The most recent example of Congress's constitutional power to enact patent statutes is the America Invents Act, passed by Congress in 2011. This Act will switch the PTO's "first-to-invent" system to a "first-inventor-to-file" system, similar to what most other countries currently use. Its other goals are to reduce patent disputes that bog down the courts and to allow the PTO to set and retain its own patent prosecution fees. *See* David Goldman, *Patent Reform Is Finally on Its Way*, CNNMONEY (June 24, 2011, 11:05 AM), http://money.cnn.com/2011/06/24/technology/patent_reform_bill/index.htm?iid=EAL (explaining the changes to patent law made by the America Invents Act).

124 Walterscheid, *supra* note 114, at 292; *see also* Graham v. John Deere Co., 383 U.S. 1, 5 (1966) ("[The Patent Clause] is both a grant of power and a limitation.").

main, or to restrict free access to materials already [publicly] available."[125] While patents give a patent holder exclusivity rights for a limited period of time, a primary justification for patent protection is to advance the progress of the arts by incentivizing innovation and disclosure.[126] Others can then improve or expand upon the public knowledge and continue making scientific progress.

Genes are, typically, not the ends but the means to progress in genetic research. Put another way, DNA molecules are usually the subject of further research.[127] Because DNA patents often claim this most basic level of biological research, they can be considered "upstream" inventions, or discoveries which require considerably more "refinement and investment" before reaching a commercial product.[128] Many DNA patents even claim analogs, or similar DNA sequences that all code for the same protein end product.[129] Patents on upstream inventions like DNA sequences may be creating a chilling effect on research: "[T]he growing number of patents on research inputs may now impede . . . research by creating an 'anticommons' in which rights holders may impose excessive transaction costs or make the acquisition of licenses . . . too burdensome to permit the pursuit of scientifically and socially worthwhile research."[130] There is concern that owners of upstream discoveries may limit follow-up research, as potential financial gains from upstream research may make researchers hesitant about sharing research findings.[131]

The plaintiffs in *Myriad* voiced this concern in the context of the Patent Clause. They argued that the BRCA patents are unconstitu-

125 *Graham*, 383 U.S. at 6. Another judicially read limitation of the Patent Clause is the fully enabling disclosure, which acts as consideration for an exclusive patent right. Walterscheid, *supra* note 114, at 300–01. In addition, novelty is a constitutional requirement. *Id.* at 359 ("Clearly, if a discovery is not new, it does not promote [the progress of science and the arts].").

126 *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–30 (1989).

127 *See, e.g.*, Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment, *supra* note 108, at 35–37 (arguing that "a genetic sequence is *biological information itself*" and thus not properly patentable (emphasis in original)).

128 *See* REAPING THE BENEFITS, *supra* note 3, at 22.

129 *See* Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181, 211–14 (S.D.N.Y. 2010) (describing the BRCA1 and BRCA2 patents-in-suit as claiming the wild-type genes, as well as mutated versions and short segments of the genes), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

130 John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCI. & L. 2002, 2002 (2005) (footnotes omitted); *see also* Heller & Eisenberg, *supra* note 68, at 698–99 (using the term "tragedy of the anticommons" to describe the "obstacles" that upstream patents may impose on biomedical research).

131 Walsh, Cho & Cohen, *supra* note 130.

tional because the Patent Clause necessarily prohibits patents that impede, rather than promote, the progress of science and the useful arts.[132] For example, several of the claims at issue in *Myriad* cover isolated, but otherwise unmodified, human DNA. The district court identified claim 1 of U.S. Patent No. 5,747,282 ("the '282 patent") as representative of this category of challenged claims: "An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ *ID* NO:2."[133] Accordingly, claim 1 of the '282 patent includes any isolated DNA molecule that codes for the naturally occurring BRCA1 protein; except for isolation, the claimed DNA is structurally identical to the DNA segment that occurs in the human body. The plaintiffs in *Myriad* alleged that Myriad's enforcement of its patents prevents anyone without a license from using or synthesizing the BRCA genes, thus stifling valuable research.[134] In the same vein, the ACLU has taken the position that patents on genetic material "slow scientific advancement[] because there is no way to invent around a gene—the gene is the basis for all subsequent research."[135]

But the net effect of upstream patents on research is far from clear. As the National Research Council of the National Academies summarizes:

> Awarding patents for [upstream] inventions may offer the possibility for the inventor to participate in any financial benefit that might result from the use of his or her discovery in the development of a drug or other useful product. On the other hand, such upstream patents could be broadly enabling in many different areas of basic research, and, if kept as a trade secret by a single company or exclusively licensed to one or very few companies they could stymie scientists more broadly in their pursuit of

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132 Brief for Plaintiffs, *supra* note 108, at 37–38.

133 U.S. Patent No. 5,747,282, col.153 ll.56–58 (filed June 7, 1995); *see* Ass'n for Molecular Pathology v. USPTO (*Myriad II*), 653 F.3d 1329, 1334 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011). Similarly, another of the defendants' patents, U.S. Patent No. 5,837,492 ("the '492 patent"), claimed the isolated DNA molecule coding for the BRCA2 protein. *See* U.S. Patent No. 5,837,492, col.167 ll.16–19 (filed Apr. 29, 1996) (claiming "[a]n isolated DNA molecule coding for a BRCA2 polypeptide, said DNA molecule comprising a nucleic acid sequence encoding the amino acid sequence . . . ."). The plaintiffs' arguments pertaining to the '282 patent also applied to the '492 argument.

134 The defendants-appellants in *Myriad* sent cease and desist letters to plaintiff-appellee researchers and doctors who used portions of the BRCA genes for patient breast cancer screening. *Myriad I*, 702 F. Supp. 2d at 204–05. The *Madey v. Duke* decision of 2002, though, "raised anew the question of the impact of research tool patents on biomedical research by clarifying that there was no general research exemption shielding academic researchers from infringement liability." Walsh, Cho & Cohen, *supra* note 130 (footnote omitted).

135 Selene Kaye, *Why Gene Patents Are Unlawful*, AM. C.L. UNION BLOG RTS. (May 22, 2009, 11:46 AM), http://www.aclu.org/2009/05/22/why-gene-patents-are-unlawful.

> basic knowledge. Patenting these upstream inventions has the advantage, therefore, of assuring universal access if licensed broadly. However, given the unique nature of human genes and the crystalline structures of human proteins, scientists may find it difficult or impossible to "invent around" the subject matter if patented and if the patent can be enforced . . . .[136]

Many studies have been conducted to clarify the effect of DNA patenting on downstream research. There is some evidence showing that "researchers are becoming more secretive and less willing to share research results or materials," but this data is being debated.[137] By and large, there seems to be little empirical evidence to support the claim that patents on DNA molecules hinder research efforts. One study of 414 researchers in for-profit, government, and non-profit entities found that only 5% of biomedical researchers checked for patent protection before beginning projects.[138] Only 1% had to delay a project due to others' patents, and none were stopped from their projects completely.[139] The consensus seems to be that there is "little empirical basis for claims that restricted access to [intellectual property] is currently impeding biomedical research."[140] "[D]espite numerous patents on upstream discoveries, academic researchers have accessed knowledge without the anticipated frictions."[141]

The complex countervailing effects of patents on the progress of genetic research are still unclear,[142] but empirical data thus far does not conclusively support the argument that DNA patenting is stalling the progress of science rather than promoting it. If the commercialization of biological research encourages more furtive or protective research practices looking forward, DNA patent holders may begin enforcing their patents rights more persistently. As of now, though,

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136 REAPING THE BENEFITS, *supra* note 3, at 22.

137 Caulfield et al., *supra* note 8, at 1092 n.28–32.

138 Walsh, Cho & Cohen, *supra* note 130.

139 *Id.*

140 *Id.* at 2003. The National Research Council of the National Academies reported similar conclusions, finding that "the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property." REAPING THE BENEFITS, *supra* note 3, at 2.

141 Walsh, Cho & Cohen, *supra* note 130.

142 For a discussion of the complex positive and negative effects that patent protection has on innovation, see generally Arti K. Rai, *Proprietary Rights and Collective Action: The Case of Biotechnology Research with Low Commercial Value*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL REGIME 288 (Keith E. Maskus & Jerome H. Reichman eds., 2005), *available at* http://scholarship.law.duke.edu/faculty_scholarship/1201 (discussing potential responses to research barriers created by patents on fundamental research tools).

an argument that DNA patents violate the spirit of the Patent Clause would likely fail without the empirical evidence to support it.

B. First Amendment Challenges to DNA Patents

Justice Cardozo reasoned in *Palko v. Connecticut* that "[f]reedom of thought . . . is the matrix, the indispensable condition, of nearly every other form of freedom. With rare aberrations a pervasive recognition of that truth can be traced in our history, political and legal."[143] "The First Amendment literally forbids the abridgment only of 'speech,'" but the Supreme Court has "long recognized that its protection does not end at the spoken or written word."[144] Additionally, the Supreme Court has recognized a "right to receive information and ideas" as "an inherent corollary of the right of free speech and press" guaranteed by the First Amendment.[145] To limit speech, the government action must pass strict scrutiny—the government must show that it has a compelling state interest and that the grant is narrowly tailored to achieve that interest.[146] Thus, the government would likely defend against a First Amendment challenge by citing the State's interest in encouraging the progress of the sciences, as provided by the Constitution's Patent Clause.

Critics of DNA patenting, including the ACLU and the plaintiffs in *Myriad*, have attempted to mount a First Amendment challenge to DNA patenting[147] by asserting that DNA, as the biological blueprint for protein production, is not merely a chemical compound but, more importantly, also a carrier of information.[148] It is a physical molecule but also an "abstract concept."[149] Because DNA molecules are difficult to invent around,[150] opponents argue that patents on DNA molecules are essentially a violation of the freedom of speech or

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143 Palko v. Connecticut, 302 U.S. 319, 326–27 (1937).

144 Texas v. Johnson, 491 U.S. 397, 404 (1989); *see also* Globe Newspaper Co. v. Superior Court, 457 U.S. 596, 604 (1982) ("[W]e have long eschewed any 'narrow, literal conception' of the [First] Amendment's terms, . . . for the Framers were concerned with broad principles . . . ." (citation omitted)).

145 Bd. of Educ. v. Pico, 457 U.S. 853, 867 (1982) (plurality opinion).

146 *See, e.g.*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 575, 582 (2001) (subjecting the Massachusetts regulations to strict scrutiny).

147 *See* Brief for American Civil Liberties Union as Amicus Curiae Supporting Appellee, *supra* note 112, at 2–7 (arguing that the patent in question cannot be granted without violating the First Amendment).

148 *Id.*; *see also* Kaye, *supra* note 52.

149 Rogers, *supra* note 4, at 21–22. Rogers even goes so far as to assert that "the gene is primarily an abstract concept." *Id.* at 22.

150 REAPING THE BENEFITS, *supra* note 3, at 22.

thought.[151] Chris Hansen, an ACLU staff lawyer, argues that "[t]here is an endless amount of information on genes that begs for further discovery, and DNA patents put up unacceptable barriers to the free exchange of ideas."[152] ACLU Executive Director Anthony Romero has opined that "granting patents that limit scientific research, learning and the free flow of information violates the First Amendment."[153]

The plaintiffs in *Myriad* supported their First Amendment argument by analogizing to copyright law.[154] The fair use doctrine in copyright law upholds First Amendment values in certain scenarios where they conflict with copyright law.[155] In addition, copyright law draws a clear dichotomy between ideas and expression—while expression is copyrightable, mere ideas are not.[156] The First Amendment, the plaintiffs argued, applies similarly to preclude ideas from being patentable.[157] If one adopts the view that DNA is indeed synonymous with information, then it becomes easier to analogize DNA to speech or thought. Judge Sweet seems to have favored this view in *Myriad I*, stating:

> The information encoded in DNA is not information about its own molecular structure incidental to its biological function, as is the case with adrenaline or other chemicals found in the body. Rather, the information encoded by DNA reflects its primary biological function: directing the synthesis of other molecules in the body . . . .[158]

The exclusion of abstract ideas from patentable subject matter,[159] though, may already preempt potential conflicts with the First

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151 Brief for Plaintiffs, *supra* note 108, at 32–36; *see also* Brief for Amicus Curiae American Civil Liberties Union, *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008), *supra* note 112, at 3–7 (asserting that the business method patent claim at issue "involve[d] pure speech and/or thought" in violation of the First Amendment).

152 Schwartz & Pollack, *supra* note 107.

153 Kaye, *supra* note 52.

154 Brief of Plaintiffs, *supra* note 108, at 32–33.

155 *See, e.g.*, Campbell v. Acuff-Rose Music, 510 U.S. 569, 579 (1994) (explaining that the fair use doctrine provides "breathing space within the confines of copyright").

156 17 U.S.C. § 102(B) (2006); *see also* Baker v. Selden, 101 U.S. 99, 104 (1879) (holding that blank account-books are not the subject of copyright).

157 Brief of Plaintiffs, *supra* note 108, at 32–33.

158 Ass'n for Molecular Pathology v. USPTO (*Myriad I*), 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010) (internal quotation marks omitted) (footnote omitted), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed* (U.S. Dec. 7, 2011).

159 *See* Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972) (finding that a mathematical algorithm is not patentable subject matter under 35 U.S.C. § 101 because it is an abstract principle). *Compare id.*, *with In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (finding that an improvement in oscilloscope technology that configured electronic circuitry to convert the input data to a form that would give a smoother-looking image was patentable because it was not an abstract idea, but a specific machine to produce a "useful, concrete, and tangible result[]").

Amendment. In other words, "[e]xisting patent doctrines, such as the abstract idea doctrine, can be interpreted to avoid the First Amendment issues."[160] The First Amendment argument would just be a redundant one if DNA molecules are deemed to be patent-ineligible abstract ideas.

However, if *Myriad II* remains good law (and DNA patents are not barred for ineligible subject matter), then the First Amendment issue would require an independent analysis.[161] As noted previously, categorizing DNA as speech or thought would probably first require a determination that DNA is primarily information.[162] Thus far, there is no case law that addresses the intersection of patent law or DNA with the First Amendment. Given the Federal Circuit's reluctance to recognize DNA as primarily a carrier of information,[163] though, other courts may be less inclined to view DNA as being synonymous with information and subject to First Amendment protection.

While the Supreme Court has extended First Amendment protection to conduct that is communicative, not just speech, it has also emphasized that in communicative conduct, "[a]n intent to convey a particularized message [is] present, and in the surrounding circumstances the likelihood [is] great that the message would be understood by those who view[] it."[164] It is not clear, in this sense, that DNA patenting restricts the free flow of speech or thought. Therefore, the Federal Circuit's unwillingness to characterize DNA as information and the stretch in viewing patenting as a restriction on speech or thought make likelihood of success for the First Amendment argument low. As the plaintiffs in *Myriad* concede, the lack of precedential support is indicative of how radical the First Amendment argument is.[165]

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160 Brief for Amicus Curiae American Civil Liberties Union, *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008), *supra* note 112, at 3.

161 *See id.* ("[I]f the Court finds [a] patent can be granted despite . . . patent doctrines, it must necessarily reach the First Amendment issues.").

162 *See supra* notes 152–158 and accompanying text.

163 Ass'n for Molecular Pathology v. USPTO (*Myriad II*), 653 F.3d 1329, 1353 (Fed. Cir. 2011) ("[T]he district court disparaged the patent eligibility of isolated DNA molecules because their genetic function is to transmit information. We disagree, as it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit."), *petition for cert. filed* (U.S. Dec. 7, 2011).

164 Spence v. Washington, 418 U.S. 405, 410–11 (1974).

165 Brief for Plaintiffs, *supra* note 108, at 37.

C. Challenges to DNA Patents as Unconstitutional Deprivations of Property

1. The Scope of a Takings Challenge

The government[166] can wield its power of eminent domain, or the taking of private property for public use, but the Takings Clause requires just compensation.[167] "The theory behind the takings clause is that individuals should not have to bear public burdens that should be borne by the community as a whole."[168]

The Federal Circuit has held that patents are not property protected by the Takings Clause of the Fifth Amendment[169] because patents grant the right to exclude rather than a positive right.[170] In other words, the owner of a patent cannot bring a takings claim against the government for unauthorized use of the patent. However, there may be another way to invoke the Takings Clause to challenge one category of DNA patents. Specifically, I posit that patents on DNA sequences that are (1) owned by the government and (2) obtained from individuals (3) without just compensation (and without permission) may face takings challenges. This type of takings challenge is very narrow and distinct from the takings challenges that the Federal Circuit declined to recognize in *Zoltek v. United States*.[171] In *Zoltek*, the property at issue was patent rights, whereas here, the property at issue is genetic material.

2. Is Patenting an Individual's Genetic Material a Deprivation of Property?

As a threshold issue, it is unclear whether a DNA patent owned by the government and derived from an individual's genetic material qualifies as a taking.[172] There are two types of takings: a possessory

166 The Supreme Court has found the Takings Clause of the Fifth Amendment to be incorporated, so it applies to both federal and state government takings. *See* Chicago, Burlington & Quincy R.R. Co. v. City of Chicago, 166 U.S. 226 (1897) (holding that state exercise of eminent domain without compensation violates the due process clause of the Fourteenth Amendment).

167 *Id.* at 240–41.

168 Lawrence O. Gostin, *Public Health Law in a New Century Part II: Public Health Powers and Limits*, 283 J. AM. MED. ASS'N 2979, 2983 (2000).

169 The Fifth Amendment provides, in relevant part, "[N]or shall private property be taken for public use, without just compensation." U.S. CONST. amend. V.

170 Zoltek v. United States, 442 F.3d 1345, 1350 (Fed. Cir. 2006).

171 *See supra* note 170 and accompanying text.

172 Although it is outside the scope of this Comment, a statute compelling the licensing of DNA patents in order to foster genetic research or increase the accessibility of genetic tests may also be attacked as a deprivation of property. The owners of affected patents

taking occurs when the government confiscates[173] or physically occupies[174] property, and a regulatory taking occurs when a government regulation leaves property with no economically viable use.[175] A government entity's use of an individual's genetic material to develop a patent is unlikely to be considered a regulatory taking or a physical occupation in the traditional sense. Whether it may be considered a confiscation is less clear, as the Supreme Court has yet to consider a takings case in the biological context.

Even assuming that patenting a DNA molecule without permission from the material's biological source would be considered a taking, the thornier question is whether genetic material is property. The Supreme Court has held that, under the Takings Clause, property refers not just to the "vulgar and untechnical sense of the physical thing with respect to which the citizen exercises rights recognized by law" but "the group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it."[176]

There is no consensus among courts about whether property rights exist in the body, and if so, how far they extend. In examining this issue, courts review historical common law interests and state law.[177] As the Ninth Circuit points out, the U.S. Supreme Court has referred to "the rights of possession and control of one's own body" as the most "'sacred'" and "'carefully guarded'" of all rights.[178] In line with this view, some courts have found quasi-property rights in bodily and genetic material,[179] but the Supreme Court has never addressed the issue directly.

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could conceivably argue that such a government regulation reduces the economic value of their patent rights by artificially mandating competition where market control would otherwise be possible.

173 Webb Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 164–65 (1980) (finding a taking when the government confiscated interest on an interpleader account).

174 Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 427 (1982) ("When faced with a constitutional challenge to a permanent physical occupation of real property, this Court has invariably found a taking.").

175 Pa. Coal v. Mahon, 260 U.S. 393, 415 (1922) (finding a taking when government regulation of property use went "too far").

176 United States v. Gen. Motors Corp., 323 U.S. 373, 377–78 (1945).

177 Newman v. Sathyavaglswaran, 287 F.3d 786, 790–93 (9th Cir. 2002) (finding that, under California law, a government coroner's harvesting of a deceased individual's corneas may be a taking of property from next of kin, requiring due process of law under the Fourteenth Amendment).

178 *Id.* at 789 (quoting Union Pacific Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891)). The Court in *Union Pacific Railway Co.* held that, in a civil tort action, a court cannot order the plaintiff, without her consent, to submit to a surgical examination before trial. 141 U.S. at 257.

179 *See, e.g.*, Brotherton v. Cleveland, 923 F.2d 477 (6th Cir. 1991) (finding unconstitutional deprivation of property in a dead body). *But see* Albrecht v. Treon, 617 F.3d 890, 898 (6th

A brief hypothetical will be useful for framing the analysis. Imagine an individual with a genetic mutation that gives his saliva extraordinary healing abilities. If he is the only person in the world to have such medicinally valuable saliva, it would be difficult to argue that he has no property claim to his own saliva or the gene that makes it unique. At the least, he has a better claim to those biological materials than any other individual in the world. He has the ability to decide, for example, whether to market his saliva and sell it for medicinal purposes.

Now, imagine that a government researcher procures a sample of the saliva legally but without obtaining the individual's notice or consent to patent the genetic material in it. The researcher subsequently identifies the mutated gene, isolates it, and purifies it in order to patent the gene and market the encoded protein. Under the Federal Circuit's *Myriad II* decision, the isolated gene would be patentable subject matter, and any resulting patent could be financially lucrative. But the constitutional issue remains: Could a patent on the gene be deemed a deprivation of the individual's property?

The hypothetical is limited, however, as demonstrated by just one change in the facts: If the genetic mutation in question can be found in any other individuals, it is less likely to be deemed the first individual's property. It would be "no more unique to [the individual] than the number of vertebrae in the spine or the chemical formula of hemoglobin."[180]

The above example may seem far-fetched, perhaps resembling something out of a science-fiction novel. But imagine a less extreme scenario, where, instead of unique saliva, an individual has mutated spleen cells with genetic material valuable to medical research. This latter scenario reflects the general facts in *Moore v. Regents of the University of California*, a seminal California case. A discussion of California case law will illustrate the ambiguity of property rights in biological materials.

The California Supreme Court in *Moore* held that there is no conversion liability in biological material removed from the human body such that they can be converted.[181] At the same time, it seemed to leave open the possibility that property rights may exist in the body if public policy required such a result, by noting "we do not purport to

Cir. 2010) (denying property rights in a dead body); Fuller v. Marx, 724 F.2d 717, 719 (8th Cir. 1984) (same). For a discussion of California cases ruling differently on the issue, see *infra* notes 203–13 and accompanying text.

180 Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 490 (Cal. 2002).

181 *Id.* at 497.

hold that excised cells can never be property . . . ."[182] In *Moore*, the plaintiff was told by doctors at a hospital that his spleen should be removed because he had hairy-cell leukemia.[183] The doctors, however, did not tell him that his cells were unique and of great scientific value.[184] They removed Moore's spleen and retained, without his knowledge or consent, a portion of the organ for study.[185] As a result of subsequent research, the university hospital established a cell line from Moore's spleen cells and obtained a financially lucrative patent for it.[186] While the court found that Moore had stated claims for breach of fiduciary duty and breach of patient consent, it declined to allow his property conversion claim to proceed because he had lost property interest in his removed spleen.[187]

On the other hand, another case interpreting California law, *Hecht v. Superior Court*, did find property interests in biological material. The petitioner's boyfriend had killed himself but saved his sperm for artificial insemination in her, as specified in his contract with the sperm bank and his will.[188] His adult children requested that the sperm be destroyed, but the decedent's girlfriend sought review after the lower court held in favor of the adult children.[189] The appellate court concluded that at the time of his death, the decedent had a property interest in his sperm because he had decision-making authority regarding them.[190] Thus, *Hecht* supports the notion of property rights in genetic material.[191]

Perhaps the seemingly inapposite results in *Moore* and *Hecht* can be reconciled by the notion that sperm and other gametic material have closer ties to a person than spleen cells because sperm encompasses the potential for reproduction—a very personal decision which produces a unique result. Put another way, human DNA, the very blueprint for individuality, may be regarded as higher on the "per-

182 *Id.* at 493.
183 *Id.* at 481.
184 *Id.*
185 *Id.*
186 *Id.* at 481–82.
187 *Id.* at 497.
188 Hecht v. Superior Court, 20 Cal. Rptr. 2d 275, 276–77 (Cal. Ct. App. 1993).
189 *Id.* at 276.
190 *Id.* at 283.
191 *See also* Newman v. Sathyavaglswaran, 287 F.3d 786, 796–97 (9th Cir. 2002) (holding that next of kin have property rights in the bodies of deceased family members).

sonhood scale" than organs or body parts that are irreplaceable once removed from the body.[192]

Under the personhood theory of property, the strength of property rights in an object is related to "the kind of pain that would be occasioned by its loss."[193] In other words, a person's property is how he defines his personhood in relation to the extrinsic world.[194] This theory is a "wholly subjective" view of property rights, focusing on the "personal embodiment or self-constitution in terms of 'things.'"[195] Thus, it seems to follow naturally that, even more than external property may shape a person's identify, a person's body should be considered essential to his personhood.

As Professor Margaret Radin points out, though, "[t]he idea of property in one's body presents some interesting paradoxes."[196] We intuitively think of property as "something in the outside world," so the body may be "too 'personal' to be property at all."[197] Yet many body parts, such as blood, hair, and organs can become "fungible commodities"—donated, sold, transfused, or transplanted—when removed from the body.[198] The line between person and thing is thus ambiguous, but Radin suggests that a "perceptible boundary" seems intuitively necessary.[199] In her view, "it seem[s] appropriate to call parts of the body property only *after* they have been removed from the system."[200]

Today, it is still unclear the extent of property rights afforded to various bodily interests.[201] Courts have not clarified the extent of any property rights in biological materials, and statutes governing indi-

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192 Margaret Jane Radin wrote an influential article on property rights through a personhood theory. *See* Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957 (1982).

193 *Id.* at 959.

194 *Id.*

195 *Id.* at 958, 961 ("This article does not emphasize how the notion of personhood might figure in the most prevalent tradition of liberal property theory: the Lockean labor-desert theory, which focuses on individual autonomy, or the utilitarian theory, which focuses on individual autonomy, or the utilitarian theory which focuses on welfare maximation.").

196 *Id.* at 966.

197 *Id.*

198 *Id.*

199 *Id.*

200 *Id.*

201 For example, "[t]oday, under federal law and all state statutory law except Louisiana, embryos [created by in vitro fertilization] do not possess rights or have legal status. In Louisiana, embryos have been given rights and limits have been imposed on how embryos may be treated." Elisa Kristine Poole, *Allocation of Decision-Making Rights to Frozen Embryos*, 4 AM. J. FAM. L. 67, 84–85 (1990).

viduals' control over their bodies in specific situations do not establish a general principle.[202]

3. Other Considerations in the Takings Analysis

If there are indeed property rights to human genetic material,[203] they would likely be limited and considered to be quasi-property.[204] For instance, there may be a limitation on the right to sell body parts.[205] And even if an individual can establish a legal property interest in his genetic material, it is still unclear whether a court would ever deem a DNA patent to be an unconstitutional taking.

That is because any takings claim related to DNA patents would be further complicated by questions about whether such a taking would be for "public use" and what "just compensation" entails.[206] The Supreme Court has broadly held that a taking is for public use if it "rationally relate[s] to a conceivable public purpose."[207] The Court has interpreted the public use requirement broadly to cover almost any conceivable government justification for a taking.[208] Presumably, then, a patent on genetic material would be for public use because,

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202 *See* Michelle Bourianoff Bray, Note, *Personalizing Personalty: Toward a Property Right in Human Bodies*, 69 TEX. L. REV. 209, 220 (1990).

203 Genetic material from non-human sources may also arguably be considered property, although ownership of such property would be more difficult to establish.

204 *See, e.g.*, Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 509–10 (Cal. 1990) (Mosk, J., dissenting) ("[L]imitation or prohibition diminishes the bundle of rights that would otherwise attach to [property], yet what remains is still deemed in law to be a protectible [sic] property interest. . . . The same rule applies to Moore's interest in his own body tissue."). Courts have often found a quasi-property right over biological material. *See, e.g.*, Davis v. Davis, 842 S.W.2d 588, 597 (1992) ("[A]ny interest that [the parties] have in . . . preembryos . . . is not a true property interest. However, they do have an interest in the nature of ownership, to the extent that they have decision-making authority concerning disposition of the preembryos, within the scope of policy set by law.").

205 While sperm may be legally sold, state laws prohibit the selling of organs for public health reasons. *Sale of Organs and Related Statutes*, U.S. DEPT. OF STATE, http://www.state.gov/documents/organization/135994.pdf (last visited Nov. 23, 2011) (listing state statutes prohibiting organ sales).

206 Just compensation, valued according to the market value to the owner as of the time of the taking, would be difficult to value and may even be zero. *See, e.g.*, Kirby Forest Indus., Inc. v. United States, 467 U.S. 1 (1984) (allowing petitioner to present evidence pertaining to the change in market value of his land between the date of taking and the date of valuation); United States v. 564.54 Acres of Land, 441 U.S. 506 (1979) (allowing respondent the fair market value of its property rather than the cost of substitute facilities).

207 Haw. Hous. Auth. v. Midkiff, 467 U.S. 229, 241 (1984).

208 *See* Kelo v. City of New London, 545 U.S. 469 (2005) (holding that governmental taking of property from one private owner to give to another for economic growth is a permissible public use).

by its nature, the subject of a patent enters the public realm and contributes to scientific innovation.

Courts may also choose to apply the Federal Circuit's view in *Myriad II* that DNA molecules, when isolated from native DNA, are chemically different entities from naturally existing DNA. Under this approach, no DNA patent would cover any molecule that exists naturally in the human body, making it even more difficult for individuals to argue that a DNA patent deprives them of any property interests in their DNA.

Ultimately, the legal outcome of a takings challenge is unclear. What is clear is that such a challenge would need to revolve around an individual and would be limited in scope to the specific DNA patent in question. In addition, even if a DNA patent is held to be a deprivation of property, it might only result in compensatory damages and not patent invalidation.

D. The Fundamental Right to Autonomy and the Fallacy of "Natural" Infringement

ACLU Executive Director Anthony Romero has asserted that "[k]nowledge about our own bodies and the ability to make decisions about our health care are some of our most personal and fundamental rights. The government should not be granting private entities control over something as personal and basic to who we are as our genes."[209]

Throughout constitutional jurisprudence, the Supreme Court has recognized certain liberties that are extratextual to the Constitution and Bill of Rights but deemed so important that they are protected under due process and equal protection. Rights deemed to be fundamental must meet strict scrutiny review rather than the mere rational basis test.[210] Contrary to Romero's assertion, though, it is unsettled whether the right to know about one's own body is a fundamental right. In determining which rights are fundamental, the Court has generally looked at the Framers' intent and, at times, which liberties are "deeply rooted in this Nation's history and tradition."[211]

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209 Kaye, *supra* note 52.

210 *See* United States v. Carolene Prods., 304 U.S. 144, 152 n.4 (1938) (articulating levels of judicial scrutiny); *see also* Wygant v. Jackson Bd. of Educ., 476 U.S. 267, 280 (1986) ("Under strict scrutiny the means chosen to accomplish the State's asserted purpose must be specifically and narrowly tailored to accomplish that purpose.").

211 Moore v. City of East Cleveland, 431 U.S. 494, 503 (1977).

Even assuming that the Court may recognize fundamental rights to know about one's own body and make health care decisions, though, Romero's argument still misses the point. First, DNA patents do not generally interfere with individuals' health care decisions. In fact, they frequently offer new health care options in the form of genetic tests, whether or not an individual may be able to afford them. Instead, Romero's argument seems to echo the oft-raised concern that individuals could be exposed to "natural" infringement, or infringement for simply carrying a patented DNA molecule in one's cells.[212]

However, natural infringement is not a legitimate concern and therefore raises no fundamental rights issues. As discussed previously, patents cannot claim naturally occurring genes that are unpurified.[213] Instead, a patent on a naturally occurring DNA sequence must claim the isolated and purified version of the DNA molecule, which, by definition, does not include any naturally occurring form inside the body.[214]

The same applies in the context of gene therapy. Gene therapy involves the transfer of "genetic sequences or genetically modified organisms to human beings for investigational or therapeutic ends."[215] Gene therapy can allow manipulation of an individual's genome, for instance by inserting a wild-type gene in place of a mutated one to fix genetic errors and prevent certain diseases. Even in these cases, a DNA patent would never reach a DNA sequence inserted into human cells because the DNA sequence becomes a different chemical molecule once it is inserted and incorporated into the human genome. As a result, there is little chance that "natural" infringement would pose any constitutional threat to DNA patenting, and concerns about fundamental rights are misplaced.

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212 *See generally* DAVID KOEPSELL, WHO OWNS YOU: THE CORPORATE GOLD RUSH TO PATENT YOUR GENES 1 (2009) ("[T]hanks to creative interpretations and applications of patent laws, parts of living things can be owned. Patents have been issued, in surprisingly large numbers, on the essential building blocks of multiple life forms.").

213 Utility Examination Guidelines, *supra* note 62, at 1093.

214 *Id.*

215 Jonathan Kimmelman, *The Ethics of Human Gene Transfer*, 9 NATURE REVS.: GENETICS 239, 239 (2008).

III. LOOKING TO THE FUTURE

While the constitutional challenges to DNA patents discussed above are largely misplaced, limited, or unlikely to succeed at this point in time, these arguments and new ones may gain traction over time. The future potential of genetic technologies should instill mixed feelings of excitement and trepidation.[216] Already, genetic testing, like BRCA screening, and genetically manipulated products, like human growth hormone, are becoming readily available. It is not difficult to imagine a day when genetic manipulation—the ability to correct genetic errors and alter physical and mental attributes like strength and concentration—becomes an option.[217] Given our world of scarce resources, though, genetic technologies will probably become accessible to some people but not to others, which may raise "profound social issues"[218] and pose "a serious and fundamental threat to our social and political system."[219]

According to Maxwell Mehlman and Jeffrey Botkin, whether people will obtain access to genetic technologies depends on three factors: "[1] whether there is a supply shortage created by technical conditions; [2] whether the technologies are covered by public or private insurance; and [3] whether people have the information they need to seek access."[220] The first of these factors—supply—could be largely dependent on the future willingness of DNA patent holders to license their technologies. A market trend in choosing to restrict licensing or other rights would affect the availability and pricing of genetic tests.

"[F]or the time being," it seems that third-party patents "rarely" pose a risk to biological research.[221] But there is some evidence that, as genetic technologies are becoming more commercially valuable, patent holders are more likely to protect their intellectual property. For example, one study found an increase, albeit a small one, in the enforcement of biological patents between 2000 and 2005: in 2000, only 3% of scientists received notifications of third party patent

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216 *See* MAXWELL J. MEHLMAN & JEFFREY R. BOTKIN, ACCESS TO THE GENOME: THE CHALLENGE TO EQUALITY 104 (1998) ("What is clear is that the genetic technologies of the future come with a curse. They promise great advances in our ability to forecast and forestall disease and to improve the capabilities of the human species.").

217 *Id.* at 90 (describing potential genetic technologies).

218 *Id.* at 87.

219 *Id.* at 105.

220 *Id.* at 87.

221 Walsh, Cho & Cohen, *supra* note 130, at 2002 (emphasis added).

rights, whereas 5% received notifications in 2005.[222] Moreover, there is empirical evidence showing that DNA patents may have an adverse impact on the availability or costs of genetic tests, not just research.[223] According to one estimate, 25% of labs have had to abandon one or more genetic tests as a result of patents,[224] and another study found that 30% of clinical labs had to abandon testing for the HFE gene after the patent issued.[225]

"The extensive use of patents can give rise to important dilemmas in terms of equitable access to the object of patents, particularly when they are useful for meeting basic human needs."[226] Assuming that rationing in our health care system will, to some extent, be based on socioeconomic factors going forward, access to genetic technologies will also be allocated according to those factors.[227] Impediments to genetic technologies, such as affordability, will disproportionately affect those who cannot afford them with their own resources.[228] A growing rift in access to genetic technologies could pose social equality issues, the severity of which cannot be predicted.[229] On one hand, acceptance and change in technology may be so gradual that society adjusts to them naturally.[230] On the other hand, there is the potential for genetic social stratification, a prospect that "clearly threatens democracy, but it is not clear how seriously."[231]

CONCLUSION

Thus far, courts in the United States have only addressed the patentability of isolated DNA molecules and genetic technologies under the Patent Act and found them to be patentable subject matter. Though constitutional challenges have been raised, they have not been addressed by any court. Yet these challenges pose interesting

222 *See id.*

223 Caulfield et al., *supra* note 8, at 1092.

224 Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G.B. Leonard & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

225 *See* Jon F. Merz, Antigone G. Kriss, Debra G. B. Leonard & Mildred K. Cho, Commentary, *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577 (2002) (discussing the award of patents for the diagnostic test for haemochromatosis).

226 LOUISE BERNIER, JUSTICE IN GENETICS: INTELLECTUAL PROPERTY AND HUMAN RIGHTS FROM A COSMOPOLITAN LIBERAL PERSPECTIVE 116 (2010).

227 MEHLMAN & BOTKIN, *supra* note 216, at 87.

228 *Id.*

229 *Id.* at 99 (envisioning a "widening gulf between the genetically privileged and the genetic underclass," having social equality consequences for a democratic society).

230 *Id.* at 105.

231 *Id.* at 103.

questions regarding the goals of our patent system, the extent of constitutional protections, and our perception of DNA. Never before has intellectual property posed questions so closely linked to personhood and individuality and challenged how we define ourselves.

This Comment focused on four emerging constitutional challenges to DNA patents and touched on the future impact of genetic technologies. Given the current constitutional jurisprudence, collaborative research environment, and relatively open licensing practices, none of the constitutional challenges to DNA patents considered seem compelling enough to succeed today.

A First Amendment or Patent Clause challenge would probably apply the most broadly to patents claiming isolated DNA molecules. The First Amendment argument would be particularly intriguing if the Supreme Court someday views DNA as not only a chemical molecule but also information. Arguments based on the Takings Clause, though narrow in scope, may also gain traction if the judicial and societal trend increasingly recognizes property interests in biological material. Even under the personhood view of property, though, it is not clear that DNA should be considered individual property. Finally, there is little risk that DNA patents would violate fundamental rights by constituting natural infringement.

Where advancements in genetic technologies will take society is anyone's guess. However, with genetic progress comes the risk of polarizing society and marginalizing equal rights. As the landscape and public perception of DNA patenting continues to evolve, the constitutional arguments discussed may become more compelling, and new constitutional issues may develop. But for the time being, critics to DNA patenting may need to turn to policy reform through the legislative process.